



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(54) Title:</b> APPARATUS AND METHODS FOR MONITORING HEMATOCRIT LEVELS OF BLOOD  <b>(57) Abstract</b>  An apparatus and method are provided for measuring the hematocrit level of blood. The presently preferred embodiment comprises a light emitting device (14) which emits an amount of light into a blood sample (12). This light travels through the blood sample to two light detecting devices (18, 20) positioned relative to the light emitting device in a predetermined geometry such that light must travel farther to reach one of the light detecting devices than to reach the other. According to the present invention, the amount of light detected by one of the light detecting devices (18, 20) is regulated so that the amount of light detected is constant. Thereafter, the amount of light detected by the unregulated light detecting device is a linear representation of the hematocrit of the blood in the blood sample. The hematocrit sensor may be used to regulate the operating parameters of an autotransfusion system to maintain the hematocrit of the blood within a predetermined range.		

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1                    APPARATUS AND METHODS FOR MONITORING  
                     HEMATOCRIT LEVELS OF BLOOD

BACKGROUND OF THE INVENTION

5                    1.    Technical Field:

                     The present invention relates to apparatus and methods  
                     used in measuring and monitoring the hematocrit of blood.  
                     More specifically the present invention relates to  
                     apparatus and methods for measuring the hematocrit of blood  
10                   by differential geometry and using the hematocrit measuring  
                     apparatus to automatically control the parameters of an  
                     autotransfusion system.

                     2.    Background Information:

15                   Most surgical procedures result in some loss of blood  
                     from associated surgical incisions. Injured patients can  
                     often experience external and internal bleeding. If blood  
                     loss from injury or surgery is substantial, it becomes  
                     necessary to replenish lost blood through transfusion.

20                   In many instances, it is possible to collect a  
                     patient's blood for use in replacing most or even all of  
                     the blood losses. It will be readily appreciated that  
                     blood collected from a wound or a surgical site will  
                     contain tissue fragments, lysed blood cells, and other  
25                   unwanted substances. Such blood must be treated for  
                     removal of unwanted substances before it is safe for  
                     reinfusion into the patient.

                     The general procedure of collecting a patient's blood,  
                     cleansing it, and then returning it to the patient is  
30                   sometimes referred to as autotransfusion. Where autotrans-  
                     fusion is possible, it is a strongly preferred way of  
                     replacing a patient's blood losses. One reason that  
                     autotransfusion is so preferred is that it avoids  
                     incompatibility problems which sometimes can occur when  
35                   giving transfusions of blood obtained from someone other  
                     than the patient. Use of a patient's own blood to replace  
                     blood losses has also become increasingly important in view

1 of issues relating to the safety of replacement blood, such  
as the prevalence of acquired immune deficiency syndrome  
(AIDS) or other diseases among blood donors in some  
locales. Because of these benefits, and others,  
5 autotransfusion is often the method of choice for  
minimizing loss of cellular blood components during diverse  
procedures ranging from surgery to plasma exchange therapy,  
and is likely to become increasingly important in the  
future.

10 The process of removing blood plasma and other  
unwanted substances without any cleansing of the blood is  
commonly referred to as plasmapheresis. Plasmapheresis has  
long been practiced through use of filters having a pore  
size large enough to pass plasma and other unwanted  
15 substances found in the blood, such as anticoagulant,  
toxins and components of lysed cells (which, for purposes  
of brevity and simplicity, shall sometimes hereinafter be  
referred to collectively as the "waste components" of  
blood), but small enough to retain intact cells, such as  
20 red blood cells, white blood cells and platelets (which  
shall sometimes hereinafter be referred to collectively as  
the "cellular components" of blood). Plasmapheresis has  
also been practiced through use of a centrifuge to separate  
plasma and other suspended waste components from the denser  
25 cellular components, and then removing the plasma and  
associated waste components.

Simple removal of plasma and associated waste  
components is not adequate to remove all waste materials  
associated with blood. It has been found that a more  
30 thorough cleansing of blood can occur if the cellular  
components are washed after the plasma is removed. United  
States Patent No. 4,631,050 describes a process of  
autotransfusion utilizing a membrane for filtration to  
separate waste components from cellular components. That  
35 patent describes an initial filtration to remove gross

1 debris, followed by addition of a washing solution to  
reconstitute the blood, and then subjecting the  
reconstituted mixture to another filtration step in order  
to remove remaining waste components. United States  
5 4,935,002 describes another autotransfusion apparatus for  
collecting, processing, and returning blood to a patient  
during or after surgery. The blood is filtered, washed,  
and separated from gross particulate refuse.

During the processing of blood for autotransfusion, it  
10 is desirable that the hematocrit of the processed blood be  
maintained in an appropriate range in order to obtain a  
thorough cleaning while minimizing problems such as  
clogging the filtration apparatus, damage to the cells,  
introducing excess solution into the patient, and the other  
15 like problems. It is believed that an appropriate range is  
from about 30% to 55%.

Differential geometry light transmission is a common  
method for measuring hematocrit. Typically, a number of  
emitters (especially from LEDs) and detectors are arranged  
20 in a predetermined geometric relationship. Light of a  
known value is emitted and the amount of light received  
along a given path is measured. These measurements are  
then applied mathematically to determine the desired  
parameter.

25 Unfortunately, while much progress has been achieved  
in this area, the full nature of light transmission and  
diffusion through blood under all circumstances has not  
been completely discovered, and thus is still unclear.  
Therefore, the mathematical equations used by the devices  
30 and methods today are based upon empirical observation by  
the users of what appears to work well. Consequently, such  
equations tend to be extremely complicated and require  
micro-computers to be implemented.

Additionally, after passing through the blood, the  
35 light signals received are highly non-linear before

1 conversion, and so require high accuracy Analog/Digital  
converters, electrical devices used for converting analog  
signals to discrete digital signals, in order to analyze  
the wide dynamic range of values encountered by the light  
5 detectors.

Further, in the devices used today, it is difficult to  
precisely control the amount of light actually emitted,  
especially since the intensity of light output versus drive  
current degrades as an LED ages.

10 With regard to the plasma and waste separators in use  
today, there is no way of continuously measuring the  
hematocrit of the blood during processing so that the  
parameters of the processing system can be adjusted to  
compensate for hematocrit readings outside of a desired  
15 range. Therefore, the plasma and waste separators cannot  
be operated at their optimum levels.

#### SUMMARY OF THE INVENTION

In accordance with the invention as embodied and  
20 broadly described herein, a hematocrit sensor apparatus is  
provided which is capable of measuring the hematocrit level  
of blood in a simple, uncomplicated manner.

More specifically, the present invention provides an  
apparatus and method for measuring the hematocrit level of  
25 blood which has been cleansed and processed for reinfusion  
into a patient by a plasma separator apparatus. The  
hematocrit sensor operates to continuously monitor the  
hematocrit level of the processed blood so that the  
hematocrit can be kept within a prescribed range. When the  
30 level gets too low, a microprocessor adjusts the parameter  
of the plasma separator apparatus in order to compensate  
for the low hematocrit level.

The presently preferred embodiment is a hematocrit  
measurement sensor comprising a light emitting device for  
35 emitting light into a blood sample and two light detecting

1 devices for detecting the light emitted into the blood  
sample. The light emitting and light detecting devices are  
arranged in a predetermined geometric pattern such that  
light traveling from the light emitting device must travel  
5 further to reach one light detecting device than to reach  
the other light detecting device, thereby forming a light  
path from the light emitting device to one light detecting  
device which is longer than the light path from the light  
emitting device to the other light detecting device. The  
10 term "path" can be considered to mean generally a straight  
line path. However, it should be noted that there will be  
some amount of light scattering as the light passes through  
the blood. Therefore, the "path" is a composite of the  
light passing from the light emitting device to the light  
15 detecting device.

According to the present invention, the amount of  
light being received by one of the light detecting devices  
is regulated to be a constant value. This regulation  
occurs through a feedback circuit wherein the light  
20 received by one of the light detecting devices is sent  
through the feedback circuit to a regulation circuit which  
compares the received light to a constant reference source  
and adjusts the drive current to the light emitting device  
so that the value received by the regulated light detecting  
25 device matches the reference value, thereby also regulating  
the output of the light emitting device.

When one of the light detecting devices is regulated  
in this way, the output of the remaining light detecting  
device takes on an inherently linear representation of  
30 hematocrit. No complicated equations are necessary to  
transform the data generated by the light detecting device  
into a value for a hematocrit measurement.

Calibration then converts the already linear  
representation into more familiar and readable units.

1       The hematocrit sensor of the present invention is  
especially useful in combination with a plasma and waste  
separator system such as, for example, that used in an  
autotransfusion system. Although many different plasma and  
5 waste separator systems may be combined with the hematocrit  
sensor, the present discussion will mainly describe one  
system in particular. In this particular system, the  
hematocrit sensor is attached to the plasma separator  
system at the output area where the processed blood is  
10 ready to be reinfused into a patient. A microprocessor may  
be used to connect the hematocrit sensor to the operations  
of the plasma separator apparatus. Limit switches may also  
be used.

      The hematocrit sensor continuously monitors the  
15 hematocrit level of the processed blood. If the hematocrit  
level falls out of a certain range (here a preferred range  
is about 45-55%), an algorithm programmed into the  
microprocessor automatically adjusts the parameters of the  
plasma separator apparatus to compensate for the too high  
20 or too low hematocrit. For example, if the hematocrit  
level is too low, the microprocessor may, as one option,  
automatically adjust the rotor speed of the plasma  
separator in order to increase agitation of the blood and  
separation of plasma and waste from the blood. If the  
25 hematocrit level is too high, a separate action will be  
automatically taken to compensate for the high level.  
Through this process, the blood being reinfused into a  
patient will always have an appropriate hematocrit level.

30       BRIEF DESCRIPTION OF THE DRAWINGS

      In the accompanying drawings, which represent the best  
mode presently contemplated for carrying out the present  
invention:

      Figure 1 is a perspective view of one embodiment of  
35 the present invention representative of "through" geometry.

1        Figure 2 is a schematic representation of "through" geometry.

      Figure 3 is a graph of linearity found using the "through" geometry before calibration.

5        Figure 4 is a graph of linearity found using the "through" geometry after calibration.

      Figure 5 is a perspective view of the preferred embodiment of the present invention representative of "back-scatter" geometry.

10       Figure 6 is a schematic representation of "back-scatter" geometry.

      Figure 7 is a graph of linearity found using the "back-scatter" geometry.

15       Figure 8 is a perspective view of an autotransfusion system wherein a hematocrit sensor is attached.

      Figure 9 is a perspective view of an optical connector within the scope of the present invention which provides a window between the flow of blood and the light emitting and light detecting devices.

20       Figure 10 is a cross-section view of the optical connector of Figure 9.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

25       The present invention is directed to a hematocrit sensor apparatus and method for measuring the hematocrit level of blood. The hematocrit sensor is especially useful in combination with a plasma separator apparatus wherein blood is processed for use in autotransfusion. However, it should also be appreciated that the teachings herein will  
30       be readily transferable to other applications involving the measurement of the hematocrit level of blood.

      Reference is first made to Figure 1, which illustrates one embodiment of the hematocrit sensor apparatus of the present invention. In Figure 1, the hematocrit sensor,  
35       identified generally by reference numeral 10, is positioned

1     beside a blood sample 12. The blood sample 12 is typically  
held in a plastic material forming an extracorporeal  
circuit through which blood is passed. The hematocrit  
sensor 10 is configured such that the hematocrit level of  
5     a flowing bloodstream can be measured by emitting light  
from one side of the blood stream, through the blood, and  
to light detectors on the other side of the blood stream.  
This embodiment is referred to as "through" geometry.

A light emitting means for emitting light into a blood  
10    sample is positioned on one side of the blood sample. It  
should be noted that the best results occur when the  
thickness of the blood sample is around one millimeter. In  
Figure 1, the light emitting means is illustrated as an  
infrared light emitting diode 14 (hereinafter "LED"). In  
15    the preferred embodiment, the LED 14 emits light at 805  
nanometers. However, the light emitting means within the  
scope of the invention may comprise any infrared diode, or  
any device that emits light in the infrared range, such as  
a laser.

20       Positioned across the blood sample from LED 14 are a  
first light detecting means for detecting light emitted  
from the light emitting means and a second light detecting  
means for detecting light emitted from the light emitting  
means. The first light detecting means is positioned to  
25    receive light emitted from the light emitting means into  
the blood sample along a first path to the first light  
detecting means. Signals put out by the first light  
detecting means corresponds to the amount of light  
detected.

30       The second light detecting means is positioned to  
receive light emitted from the light emitting means into  
the blood sample such that light emitted from the light  
emitting means must travel farther to reach the second  
light detecting means than to reach the first light  
35    detecting means, thereby forming a second path from the

1 light emitting means to the second light detecting means  
which is longer than the first path from the light emitting  
means to the first light detecting means. Signals put out  
by the second light detecting means correspond to the  
5 amount of light detected.

In Figure 1, these light detecting means are  
illustrated by a first diode 18 and a second diode 20.  
First diode 18 and second diode 20 are positioned to detect  
light emitted from LED 14 into the blood sample. Signals  
10 thereafter output by the first diode 18 and the second  
diode 20 correspond to the amount of light detected.  
Although in the preferred embodiment PIN diodes are used,  
any quality photodetector would be sufficient for use as  
the light detecting means.

15 In the present invention, positioning of the first and  
second diodes, 18 and 20, and the LED 14, is important to  
create the "through" geometry. LED 14 is positioned such  
that the path of light from LED 14 through blood sample 12  
and to first diode 18 is shorter than the path of light  
20 from LED 14 through blood sample 12 and to second diode 20.  
Thus, by specific positioning of LED 14 and first and  
second diodes, 18 and 20, there is formed a short first  
path and a long second path.

It should be noted that correct positioning of the  
25 devices may vary with respect to distances between LED 14  
and first and second diodes, 18 and 20. In the preferred  
embodiment, the long second path is two millimeters and the  
short first path is one millimeter. It has also been found  
successful, for example, to have a long second path two and  
30 one half millimeters and a short first path one millimeter,  
or to have a long second path three millimeters, and a  
short first path two millimeters. It appears that it is  
the difference in the path lengths and not particularly the  
magnitude of that difference that is important to the  
35 present invention. The path lengths may be adjusted.

1       However, it is important to note that the farther away the  
detectors are placed from the emitters, the more power  
would be needed for the emitters to emit an amount of light  
which will reach the detectors.

5       Although it can be appreciated that many alternate  
configurations are available, one preferred configuration  
for forming this "through" geometry embodiment is to place  
first and second diodes, 18 and 20, beside each other on  
one side of the blood sample. LED 14 is then placed on the  
10       opposite side of the blood sample along a center line  
between the two diodes, and then offset longitudinally  
toward one diode and away from the other. The side to  
which LED 14 is offset forms the short first path, and the  
remaining side forms the long second path. In Figure 1,  
15       the path to first diode 18 is the short first path, while  
the path to second diode 20 is the long second path.

As discussed, light emitted from LED 14 through the  
blood sample is detected by first diode 18 and second  
diode 20. According to the present invention, it is  
20       necessary to regulate the amount of light detected on one  
path so that the amount detected remains a constant. The  
device within the scope of the present invention further  
comprises regulating means for regulating the intensity of  
light emitted by the light emitting means such that the  
25       received light on one of the paths remains at a constant  
value.

Another feature of the present invention are  
amplifying means for performing offset and gain calibration  
of the signals output from the light detecting means. An  
30       amplification signal is provided which is a linear  
representation of the hematocrit of blood in the blood  
sample. Within the scope of the present invention, one  
amplifying means is an offset and gain calibration  
amplifier.

35

1           In the "through" geometry, the amount of light  
detected on the short first path is regulated by  
electrically connecting first diode 18 to LED 14 through a  
feedback circuit. This feedback circuit is illustrated in  
5       Figure 2 and generally labeled 22. When LED 14 is  
energized, light is emitted into the blood. The light  
received by the first diode 18 is amplified and sent  
through feedback circuit 22 to a regulation circuit 24. At  
the regulation circuit 24, the received light is compared  
10      to a constant reference source 26, and the drive current to  
the light emitting device is adjusted so that the value  
received by first diode 18 matches the value of the  
reference source 26, thereby regulating the output of the  
light emitting device and ensuring that the amount of light  
15      received by the first diode 14 remains at a constant value.

Once light received on the short first path is  
regulated, the amount of light received on the long path is  
then analyzed. Second diode 20 of the long second path  
outputs a signal corresponding to the amount of light it  
20      receives. The resulting output has been found to provide  
a linear representation of hematocrit. Additionally, it  
has been found that the output signal of this second  
diode 20 decreases as the hematocrit rises. This light is  
amplified and then fed to a standard "offset and gain"  
25      calibration amplifier known in the art and labelled  
generally in Figure 2 as 28.

It is important to note that in devices in use today  
where hematocrit is measured by light detecting diodes  
which detect light emitted into the blood from light  
30      emitting diodes, the output signals of the light detecting  
diodes cannot be easily analyzed. Complex equations must  
be used in order to analyze and form the data into a linear  
hematocrit reading. Microprocessors and A/D converters are  
necessary to obtain the hematocrit measurements.

1 In contrast, with the embodiment of the present  
invention, when the amount of light traveling on one path  
is regulated, the output from the unregulated path, without  
the need of complex mathematical process, forms a linear  
5 hematocrit reading. Figure 3 illustrates the linearity of  
the output from the "through" geometry.

Calibration of the output then converts the already  
linear representation into more familiar and readable  
units. Figure 4 illustrates the linearity of the output  
10 from the "through" geometry after calibration.

Although the "through" geometry is successful and  
demonstrates the practicality of the present invention,  
there are some limitations to the embodiment. For example,  
blood is a relatively dense optical medium. Therefore, the  
15 blood flow channels which are used with the "through"  
geometry must be very narrow in order to allow adequate  
light levels to penetrate. This can be undesirable due to  
the nature of the extracorporeal flow rates expected. A  
narrow flow channel was too confining.

20 Therefore, a second and preferred embodiment was  
developed. This embodiment, illustrated in Figure 5  
comprises a "back-scatter" geometry. Here, an LED 30 is  
positioned on the same side of the blood sample as the  
light detecting means, as opposed to being positioned on  
25 the opposite side as with the "through" geometry. The  
light detecting means are illustrated in Figure 4 as a  
short path diode 32 and a long path diode 34. Again, the  
path to diode 34 is longer than the path to diode 32. As  
the light emitted into the blood stream does not have to  
30 fully penetrate the blood stream for detection by the light  
detecting means to occur, the thickness of the blood flow  
channel is not at issue. It is important to note that the  
back-scatter path is not a simple path. The back-scattered  
light detected is not simply one path of light, but more of  
35 an aggregation of light reflected back through the blood.

1     Figure 4 presents a simplified illustration of a back-scattered light path.

         In the "back-scatter" geometry, the long second path is regulated so that the amount of light detected remains at a constant value. (Recall that in the "through" geometry, the short first path is regulated.) The long path diode 34 is electronically connected to LED 30 by a feedback circuit, illustrated in Figure 6 and labelled generally as 42. The amount of light detected by long path diode 34 is amplified and fed to a regulation circuit 44. This circuit then compares the light received by the long path diode 34 to a constant reference source 46 and adjusts the drive current to LED 30 so that the value received on the long second path matches the value of constant reference source 46. As with the "through" geometry, this holds constant the amount of light received by one path.

         The signal is then fed to a standard "offset and gain" calibration amplifier 48. The resulting output is the linear hematocrit representation. In the back-scatter geometry, as the hematocrit rises, the output signal of the short first path increases. By contrast, it should be noted that in the "through" geometry, the situation is reverse. There, as the hematocrit rises, the output signal of the long second path decreases.

         Figure 6 illustrates the linearity of the output signals of the "back-scatter" geometry. As can be seen from the graph of Figure 7, with the device of the present invention, complex computer manipulations are again not necessary to form the output signals into a linear hematocrit reading. Calibration, however, converts the signals into more familiar and usable terms. Figure 7 illustrates the calibrated output signals.

         It is within the scope of the present invention for the light emitting diode and the light detecting diodes to be arranged either directly against the blood sample

1     itself, or separated from the bloodstream by a clear  
window. Although it has been found that better results are  
obtained when a window is not used, it is more practical to  
use a window to separate the blood from the diodes. One  
5     reason for this is the expense of the diodes. Without an  
isolating window, the diodes would be in direct contact  
with the blood and would have to be constantly replaced due  
to contamination. Another reason is that most applications  
of the hematocrit sensor will be in extracorporeal  
10    circuits, where the clear window may already be present.  
Figures 1 and 4 illustrate use of a window 52 separating  
the diodes from the blood stream 12.

It is also within the scope of the present invention  
to employ conveying means, in communication with the light  
15    emitting means and the light detecting means, for  
transmitting light from the light emitting means to the  
blood and to the light detecting means along first and  
second paths. The first conveying means is in  
communication with the first light emitting means and  
20    transmits light from the light emitting means to the blood.  
The second conveying means is in communication with the  
first light detecting means and transmits light to the  
first light detecting means through the blood along the  
first path. The third conveying means is in communication  
25    with the second light detecting means and transmits light  
to the second light detecting means through the blood along  
the second path. The preferred conveying means is  
illustrated in Figure 5 as first, second, and third plastic  
fibers, 54, 56, and 58 respectively. It should be  
30    appreciated that glass fibers may also be used within the  
scope of the present invention.

In the preferred embodiment, one millimeter diameter  
fibers are placed sided by side next to a blood sample.  
The light emitting means and the light detecting means are  
35    placed on the outer ends of the fibers, and the free ends

1 of the fibers are then placed against the window of the  
blood stream. As these fibers are one millimeter in  
diameter, the measurement taken center to center would be  
two millimeters to the long second path versus one  
5 millimeter to the short first path.

In Figure 5, LED 30 is illustrated as positioned  
against the end of first fiber 54. Short path diode 32 is  
positioned against the end of second fiber 56. Long path  
diode 34 is positioned against the end of third fiber 58.  
10 Although the preferred embodiment employs the use of  
plastic fibers, glass fibers or no fibers at all, may also  
be used.

For example, Figure 1 illustrates the first diode 18  
and second diode 20 directly against the window 38 of blood  
15 stream 12. However, it is possible to add glass or plastic  
fibers to the embodiment and the embodiment would still  
perform within the scope of the present invention.

Further, the hematocrit measuring device of the  
present invention also effectively operates when the light  
20 source is pulsed. Pulsing neither adds to nor detracts  
from the methodology described.

A novel method for measuring the hematocrit of blood  
using the hematocrit sensor of the present invention is  
also disclosed. The first step of the novel method  
25 comprises positioning a light emitting device so as to emit  
light into a blood sample. The second step is to energize  
the light emitting device such that light is emitted  
through the blood sample.

Next, a first light detecting device is positioned  
30 such that it receives light emitted from the light emitting  
device into the blood along a first path, and a second  
light detecting device alongside the blood sample such that  
it also receives light emitted from the light emitting  
device into the blood. The light emitting device, the  
35 first light detecting device and the second light detecting

1 device are all positioned in a predetermined geometric relationship, whereby the second path is longer than the first path.

5 A feedback circuit is then provided for monitoring the second light detecting device, and regulating the amount of light received by the second light detecting device so that it remains at a constant value. This amount of light may be amplified and sent through the feedback circuit to a regulation circuit where it is compared to a constant  
10 reference source. The drive current to the light emitting device is then automatically adjusted so that the value of the amount of light received by the second light detecting device matches the reference value. This thereby also regulates the amount of light emitted by the light emitting  
15 device.

The final step comprises amplifying the light received by the first light detecting device and feeding the amplified light to a standard offset and gain calibration amplifier in order to generate an output signal of the  
20 first light detecting device which will be a linear representation in familiar units of the hematocrit of blood in the blood sample. By this novel method, a linear hematocrit reading is obtained without the need for complex equations processed by a microcomputer.

25 Another important aspect of the hematocrit sensor of the present invention is its possible use with a plasma separator apparatus such as used in an autotransfusion system. Typical autotransfusion systems in the prior art do not have the capability to constantly monitor and  
30 maintain the hematocrit levels of the blood as they process the blood for reinfusion into a patient.

Use of the novel hematocrit sensor with a plasma separator apparatus of an autotransfusion system will be described below, with reference to Figure 8. Having the  
35 hematocrit sensor 10 attached to the autotransfusion system

1 of Figure 8, identified generally by reference numeral 66,  
allows automatic monitoring and adjustment of the  
autotransfusion system. It should be realized that  
although a particular autotransfusion system is herein  
5 described, use of the device of the present invention is  
not limited to this particular autotransfusion system. Any  
comparable plasma separator system may be used.

Autotransfusion system 66 is configured for use in  
recovering blood from a surgical site, so that the blood  
10 can be cleaned and returned to the patient. A sucker 68 is  
used to aspirate blood from a surgical site. A source of  
anticoagulant 70 is coupled to sucker 68 so that mixing of  
anticoagulant occurs quickly, thereby minimizing formation  
of blood clots. Aspirated blood and anticoagulant are  
15 drawn into a conventional blood collection reservoir 72,  
which includes a filter 74 having a pore size which will  
remove large particles such as blood clots, pieces of  
tissue, orthopedic cement, and the like, but which will  
pass cellular components of blood. Blood collection  
20 reservoir 72 also serves to effect defoaming of blood  
collected therein.

A roller pump 76 is advantageously used to pump blood  
from collection reservoir 72 into a plasma separator,  
depicted generally by reference numeral 80. A wash  
25 solution, preferably saline, is also pumped into plasma  
separator 80 from a source 82. The wash solution is mixed  
with partially cleansed blood by rotors (not shown) within  
the plasma separator 80 in order to effect more thorough  
separation of waste components from the cellular components  
30 of the blood being processed by the plasma separator.  
Cleansed blood processed by plasma separator 80 is  
collected in a blood collection bag 86, and from there it  
is returned to the patient, typically by conventional  
gravity infusion. Plasma, anticoagulant, and other waste  
35 components of the blood are collected in a waste collection

1 bag 88, which may be discarded. A presently preferred  
plasma separator is described in United States Patent  
Application Serial No. 07/844,232, filed March 2, 1992,  
which is hereby incorporated by reference.

5 Before blood is collected in blood collection bag 86,  
it passes through the area where the hematocrit sensor 10  
is located. As can be seen in Figure 8, the hematocrit  
sensor 10 is positioned within the sensor head 90 between  
10 the outlet of the plasma separator 80 and the blood  
collection bag 86. Not only is hematocrit sensor 10  
physically connected to autotransfusion system 66, but it  
may also be electronically connected by means of a  
microprocessor which controls the operating parameters of  
the autotransfusion system.

15 After the blood is processed by the system, the blood  
flows past the hematocrit sensor where the hematocrit level  
of the blood is measured. If the hematocrit level falls  
out of a certain range, (again, the preferred range here  
being about 45-55%), an algorithm programmed into the  
20 microprocessor will automatically adjust at least one  
parameter of the plasma separator apparatus so as to  
compensate for the too high or too low hematocrit. For  
example, if the hematocrit level is too low, the  
microprocessor may, as one option, automatically adjust the  
25 speed of rotors within the plasma separator in order to  
increase agitation of the blood, and separation of plasma  
and waste from the blood. Another option may be to  
decrease the rate of pumping blood into the system. With  
less blood flowing through, performance of the system can  
30 increase. Alternatively, if the hematocrit level is too  
high, a separate action can be automatically taken to  
compensate for the high level.

Thus, it can be seen that through this process, the  
blood being reinfused into a patient will always have an  
35 appropriate hematocrit level.

1           It is conceivable that many different algorithms may  
be programmed into the microprocessor so that a variety of  
actions will be available to compensate for either a low or  
high hematocrit level. Additionally, the microprocessor  
5   may also be programmed so that if the hematocrit level  
falls to an unacceptable and uncorrectable level, the  
system will automatically stop, and an alarm sound so as to  
alert an operator to examine the system.

          This programming ability is an advantage over  
10 conventional systems. In conventional systems, there is no  
way of measuring and automatically controlling the  
hematocrit level of blood should it be found to be too high  
or low. An operator must always measure the hematocrit  
separately, and then must make any needed adjustments  
15 manually. Constant supervision is necessary.

          With the hematocrit sensor of the present invention,  
however, the hematocrit level of the blood is constantly  
monitored, and any necessary adjustments to the  
autotransfusion system automatically takes place by means  
20 of the microprocessor linking the hematocrit sensor and the  
autotransfusion system. Only when the microprocessor  
cannot adjust the system enough to correct the too high or  
low hematocrit, will an operator have to step in and solve  
the problem.

25           A further novel aspect of the present invention is an  
optical connector used with the hematocrit sensor to  
separate the components of the hematocrit sensor from  
direct contact with the blood. The optical connector is  
illustrated in Figures 9 and 10 and labelled 100. Optical  
30 connector 100 is comprised of a generally hollow member 102  
adapted to receive a blood sample therein with respect to  
which hematocrit is to be measured. An optically clear  
flexible optical window 106 is positioned on the generally  
hollow member 102. Through optical window 106, the blood  
35 sample within the generally hollow member 102 may be

1 visually accessed for measurement of its hematocrit. A  
support 110 for securing the optical fibers to the  
generally hollow member may extend from the flexible  
optical window 106 substantially perpendicularly from the  
5 generally hollow member 102. As seen in Figures 9 and 10,  
fibers 54, 56 and 58 are secured within support 110 against  
flexible optical window 106.

Optical window 106 should be completely free of  
optical defects. The presently preferred material for  
10 optical window 106 is a PVC resin. However, any material  
which is flexible and provides optical clarity is within  
the scope of the present invention.

As can be seen in Figure 9, optical connector 100 is  
placed within the sensor head 90 of hematocrit sensor 10,  
15 and the generally hollow member 102 is connected to a blood  
flow channel 114. As the generally hollow member 102 is  
connected to blood flow channel 114, flexible optical  
window 106 is positioned over fibers 54, 56, and 58. By  
this positioning of the flexible optical window tube 102  
20 over fibers 54, 56, and 58, flexible optical window 106 is  
pressed against fibers 54, 56, and 58. As optical  
window 106 is flexible, it forms around and presses firmly  
against the fibers, thus securing the fibers firmly in  
place so as to provide visual access to the blood sample  
25 while protecting the fibers from direct contact with the  
blood. With use of the optical connector 100, the fibers  
never directly contact the blood, and so do not have to be  
replaced with each use.

When fibers 54, 56 and 58 are pressed against flexible  
30 optical window 106, flexible optical window 106 conforms  
its shape to the ends of the fibers so that the flexible  
optical window 106 rests against fibers 54, 56 and 58  
tightly. Generally, because of tolerances, it is difficult  
to align fibers 54, 56 and 58 so that the end of each fiber  
35 terminates against the optical window. To compensate for

1 this tolerance variation, flexible optical window 106 is  
flexible enough so that the fibers will mate tightly with  
the optical window and allow detection of the blood sample  
through the flexible optical window 106 while preventing  
5 contact between the blood and the detectors.

In one embodiment, once the fibers are positioned into  
support 110, they are glued into place.

Optical connector 100 is a disposable component of the  
hematocrit sensor system. Once used, it may be removed  
10 from sensor head 90 and thrown away. Although it is  
substantially cylindrical in the preferred embodiment,  
other shapes are also within the scope of the present  
invention.

In Figure 9, it can be seen that optical connector 100  
15 lies inside of sensor head 90. Sensor head 90 is comprised  
of a lid 120 and a bottom half 124 connected on one side by  
a hinge 126. When lid 120 of sensor head 90 is opened,  
optical connector 100 may be placed inside. A locking  
arm 122 used to allow access to the inside of sensor  
20 head 90 by engaging lid 120 to bottom half 124, or  
disengaging lid 120 from bottom half 124, is connected to  
bottom half 124 of sensor head 90. Locking arm 122 pivots  
upwards around its point of connection with bottom half 124  
of sensor head 90 and engages with lid 120, thus securing  
25 lid 120 to bottom half 124 and thereby placing sensor  
head 90 into a closed position. When locking arm 122 is  
pivoted downward, it disengages with lid 120, and allows  
lid 120 to be lifted, thereby placing sensor head 90 into  
an opened position wherein optical connector 100 can be  
30 placed inside, or withdrawn.

Another important aspect of the present invention  
which is disclosed herein is the novel method for  
automatically controlling the operation of an  
autotransfusion system by using hematocrit measurement to  
35 control parameters of a plasma separator apparatus. The

1 first step of this method comprises attaching a  
hematocrit sensor to a plasma separator apparatus wherein  
cellular components of blood, red blood cells, white blood  
cells, and platelets, are separated from such waste  
5 components as plasma, anticoagulant, toxins, and other  
relatively small molecules. Once attached, the hematocrit  
sensor can then constantly monitor the hematocrit level in  
the blood during operation of the separator apparatus, so  
that the operation of the separator apparatus can be  
10 adjusted in order to keep the hematocrit level within a  
desired range. Thus, with the hematocrit sensor of the  
present invention, the operator of a plasma separator  
apparatus can know when adjustments to the operating  
parameters of the plasma separator device are necessary in  
15 order to obtain high quality blood, and can take action  
immediately after being notified by readings of the  
hematocrit sensor.

The hematocrit sensor of the present invention may be  
used with many different types of autotransfusion systems.  
20 In one particular system, however, blood is pumped through  
a plasma separator apparatus, where rotating means within  
the apparatus for producing movement of cellular components  
of blood causes turbulence. This thereby increases the  
filtration of waste components. Through readings from the  
25 hematocrit sensor of the present invention, the operator of  
the plasma separator apparatus would be able to know  
whether the speed of the rotor means should be increased or  
decreased in order to obtain the right amount of filtration  
necessary to produce a hematocrit level within a desired  
30 range.

It can be appreciated that the hematocrit sensor may  
not only be physically coupled with the autotransfusion  
system, but it may also be electronically joined to the  
plasma separator apparatus of the autotransfusion system.  
35 One possible way would be through connection by a

1     microprocessor.     The microprocessor could function to  
process measurements obtained by the hematocrit sensor. If  
the measurements do not fall within a predetermined  
acceptable range, the microprocessor can then automatically  
5     adjust at least one operating parameter of the plasma  
separator apparatus in order to bring the hematocrit back  
to the desired range. Various algorithms can be programmed  
into the microprocessor such that each hematocrit reading  
automatically produces a different and appropriate response  
10    from the plasma separator apparatus.

Other ways for the hematocrit sensor to be  
electronically linked to the plasma separator apparatus are  
by using discrete circuitry, or by using a limit switch.  
The regulation circuit of the present invention can be used  
15    to hold the motor of the apparatus constant. The inherent  
linearity of the signal outputs of the present device is  
used to control the circuits and switches.

It will be readily appreciated that the hematocrit  
sensor of the present invention may be used with many types  
20    of different systems, as well as with other apparatus such  
as heart and lung machines.

It should also be noted that one use of the hematocrit  
sensor may be to detect air in the blood. If the  
hematocrit is low, during conditions when there should be  
25    large quantity of blood cells, it may be deduced that air  
is present and the machine can be stopped. This capability  
can be useful, for example, when the blood is in a bag  
which is gravity connected to a patient. It is important  
not to force air into the patient.

30     Further, the hematocrit sensor may be used with  
autotransfusion system to indicate the beginning or end  
of each autotransfusion cycle. If the hematocrit  
measurement of blood before and after being processed by  
autotransfusion system is known, then by monitoring  
35    hematocrit measurements as registered by the hematocrit

1 sensor, an operator could identify the beginning and end of  
each cleansing cycle.

The present invention may be embodied in other  
specific forms without departing from its spirit or  
5 essential characteristics. The described embodiments are  
to be considered in all respects only as illustrative and  
not restrictive, and the scope of the invention is  
indicated by the appended claims rather than by the  
foregoing description. All changes which come within the  
10 meaning and range of equivalency of the claims are to be  
embraced within their scope.

What is claimed is:

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1           1. An apparatus for measuring the hematocrit of  
blood comprising:

light emitting means for emitting light into a  
blood sample;

5           first light detecting means for detecting light  
emitted from the light emitting means, said first  
light detecting means positioned to receive light  
emitted from the light emitting means into the blood  
sample along a first path to the first light detecting  
10 means, the first light detecting means outputting a  
signal corresponding to the amount of light detected;

second light detecting means for detecting light  
emitted from the light emitting means, said second  
light detecting means being positioned to receive  
15 light emitted from the light emitting means into the  
blood sample, such that light emitted from the light  
emitting means must travel farther to reach the second  
light detecting means than to reach the first light  
detecting means, thereby forming a second path from  
20 the light emitting means to the second light detecting  
means which is longer than the first path from the  
light emitting means to the first light detecting  
means, the second light detecting means outputting a  
signal corresponding to the amount of light detected;  
25 and

regulating means for regulating the intensity of  
light emitted by the light emitting means such that  
the received light on one of the paths remains at a  
constant value.

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2. An apparatus for measuring the hematocrit of  
blood as defined in claim 1, wherein the light emitting  
means comprises an infrared light emitting diode.

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1           3. An apparatus for measuring the hematocrit of  
blood as defined in claim 1, wherein the light emitting  
means comprises an infrared laser.

5           4. An apparatus for measuring the hematocrit of  
blood as defined in claim 2, wherein the infrared light  
emitting diode emits light at approximately 805  
nanometers.

10          5. An apparatus for measuring the hematocrit of  
blood as defined in claim 1, wherein at least one of the  
light detecting means comprises a PIN diode.

15          6. An apparatus for measuring the hematocrit of  
blood as defined in claim 1, further comprising amplifying  
means for providing an amplified signal which is a linear  
representation of the hematocrit of blood in the blood  
sample.

20          7. An apparatus for measuring the hematocrit of  
blood as defined in claim 1, wherein at least one of the  
light detecting means comprises a photodetector.

25          8. An apparatus for measuring the hematocrit of  
blood as defined in claim 1, further comprising:

first conveying means, in communication with the  
light emitting means, for transmitting light from the  
light emitting means to the blood;

30          second conveying means, in communication with the  
first light detecting means, for transmitting light  
passing through the blood to the first light detecting  
means along the first path; and

third conveying means, in communication with the  
second light detecting means, for transmitting light

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1           passing through the blood to the second light  
          detecting means along the second path.

          9. An apparatus for measuring the hematocrit of  
5   blood as defined in claim 8, wherein the conveying means  
     comprises glass fibers.

          10. An apparatus for measuring the hematocrit of  
     blood as defined in claim 8, wherein the conveying means  
10   comprises plastic fibers.

          11. An apparatus for measuring the hematocrit of  
     blood as defined in claim 1, further comprising an optical  
     connector, said optical connector comprising a generally  
15   hollow member adapted to receive therein the blood sample  
     with respect to which hematocrit is to be measured, and an  
     optically clear flexible optical window positioned on the  
     generally hollow member through which blood can be  
     monitored.

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          12. An apparatus for measuring the hematocrit of  
     blood as defined in claim 11, further comprising a support  
     extending from the flexible optical window substantially  
     perpendicularly from the cylindrical member, for securing  
25   to the cylindrical member the light emitting and light  
     detecting means, thereby allowing the light emitting and  
     light detecting means access to the blood sample without  
     direct contact with the blood sample.

30           13. An apparatus for measuring the hematocrit of  
     blood as defined in claim 11, wherein the flexible optical  
     window comprises a polyvinylchloride resin material.

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1           14. An apparatus for measuring the hematocrit of  
blood as defined in claim 11, wherein the flexible optical  
window comprises an optically clear material.

5           15. An apparatus for measuring the hematocrit of  
blood comprising:

light emitting means for emitting light into a  
blood sample;

10           first light detecting means for detecting light  
emitted from the light emitting means, said first  
light detecting means positioned to receive light  
emitted from the light emitting means into the blood  
sample along a first path to the first light detecting  
means, said first light detecting means outputting a  
15           signal corresponding to the amount of light detected;

            second light detecting means for detecting light  
emitted from the light emitting means, said second  
light detecting means being positioned to receive  
light emitted from the light emitting means into the  
20           blood sample, such that light emitted from the light  
emitting means must travel farther to reach the second  
light detecting means than to reach the first light  
detecting means, thereby forming a second path from  
the light emitting means to the second light detecting  
25           means which is longer than the first path from the  
light emitting means to the first light detecting  
means, the second light detecting means outputting a  
signal corresponding to the amount of light detected;

30           first conveying means, in communication with the  
light emitting means, for transmitting light from the  
light emitting means to the blood;

            second conveying means, in communication with the  
near detecting means, for transmitting to the first  
light detecting means light passing through the blood  
35           along the first path;

1           third conveying means, in communication with the  
far detecting means, for transmitting to the second  
light detecting means light passing through the blood  
along the second path; and  
5           regulating means for regulating the intensity of  
light emitted by the light emitting means such that  
the received light on one of the paths remains at a  
constant value.

10           16. An apparatus for measuring the hematocrit of  
blood as defined in claim 15, wherein the light emitting  
means comprises an infrared light emitting diode.

15           17. An apparatus for measuring the hematocrit of  
blood as defined in claim 15, wherein the light detecting  
means comprises a photodiode.

20           18. An apparatus for measuring the hematocrit of  
blood as defined in claim 15, wherein the conveying means  
comprises glass fibers.

25           19. An apparatus for measuring the hematocrit of  
blood as defined in claim 15, wherein the conveying means  
comprises plastic fibers.

30           20. An apparatus for measuring the hematocrit of  
blood as defined in claim 15, further comprising amplifying  
means for performing offset and gain calibration of the  
signals output from the first and second light detecting  
means so as to provide an amplification signal which is a  
linear representation of the hematocrit of blood in the  
blood sample.

35           21. A method for measuring the hematocrit of blood  
comprising the steps of:

- 1 (a) positioning a light emitting device so as to  
emit light through a blood sample;
- (b) energizing the light emitting device such  
that light is emitted through the blood sample;
- 5 (c) positioning a first light detecting device  
such that it receives light emitted from the light  
emitting device through the blood sample along a first  
path;
- (d) positioning a second light detecting device  
10 such that it receives light emitted from the light  
emitting device through the blood sample along a  
second path, whereby the second path is longer than  
the first path;
- (e) providing a feedback circuit for monitoring  
15 the light detected by the second light detecting  
device;
- (f) regulating the intensity of light emitted by  
the light emitting device so that the amount of light  
detected by the second light detecting device remains  
20 at a constant value; and
- (g) detecting the amount of light received by  
the first light detecting device.

22. A method for measuring the hematocrit of blood as  
25 defined in claim 21, further comprising the step of  
providing an amplifier which receives and converts input  
signals from the light detecting devices, so as to generate  
an amplified output signal which is a linear representation  
of the hematocrit of blood in the blood sample.

30

23. A method for measuring the hematocrit of blood  
comprising the steps of:

- (a) positioning a light emitting device so as to  
emit light through a blood sample;

35

1 (b) energizing the light emitting device such  
that light is emitted through the blood sample;

(c) positioning a first light detecting device  
such that the first light detecting device receives  
5 back-scattered light from light emitted from the light  
emitting device through the blood sample along a first  
path;

(d) positioning a second light detecting device  
such that it receives back-scattered light from light  
10 emitted from the light emitting device into the blood  
sample along a second path, whereby the light emitting  
device, the first light detecting device, and the  
second light detecting device are all positioned in a  
predetermined geometric relationship, and whereby the  
15 second path is longer than the first path;

(e) providing a feedback circuit for monitoring  
the light detected by the first light detecting  
device;

(f) regulating the intensity of light emitted by  
20 the light emitting device so that the amount of light  
detected by the first light detecting device remains  
at a constant value; and

(g) detecting the amount of light received by  
the second light detecting device.

25

24. A method for measuring the hematocrit of blood as  
defined in claim 23, further comprising the step of  
providing an amplifier which receives and converts signals  
from the light detecting devices so as to generate an  
30 amplification signal which is a simple linear  
representation of the hematocrit of blood in the blood  
sample.

25. An apparatus for regulating the operation of a  
35 plasma separator apparatus to keep the hematocrit

1 measurement of blood output therefrom within a  
predetermined range, comprising:

5 a plasma separator apparatus for removing  
unwanted waste components from the blood in order to  
cleanse the blood; and

monitoring means for measuring the hematocrit of  
the cleansed blood outputted from the plasma separator  
apparatus, and for thereafter automatically regulating  
operating parameters of the plasma separator apparatus  
10 so as to maintain a hematocrit of the blood within a  
predetermined range.

26. An apparatus as defined in claim 25 wherein said  
plasma separator apparatus comprises separating means for  
15 separating plasma from the cellular components of blood and  
washing means for further cleansing of the blood.

27. An apparatus as defined in claim 25, wherein the  
monitoring means for automatically regulating operating  
20 parameters of the plasma separator apparatus comprises a  
hematocrit sensor for measuring the hematocrit of blood,  
interconnected with the plasma separator apparatus by a  
microcomputer, said hematocrit sensor comprising light  
emitting means for emitting light into a blood sample,  
25 first light detecting means for detecting light emitted  
from the light emitting means, said first light detecting  
means positioned to receive light emitted from the light  
emitting means into the blood sample along a first path,  
and the first light detecting means outputting a signal  
30 corresponding to the amount of light detected, second light  
detecting means for detecting light emitted from the light  
emitting means, said second light detecting means being  
positioned to receive light emitted from the light emitting  
means into the blood sample along a second path, such that  
35 light emitted from the light emitting means must travel

1 farther to reach the second detecting means than to reach  
the first light detecting means, thereby forming a second  
path from the light emitting means to the second light  
detecting means which is longer than the first path from  
5 the light emitting means to the first light detecting  
means, and regulating means for regulating the intensity of  
light emitted by the light emitting means such that the  
received light on one of the paths remains at a constant  
value.

10

28. An apparatus as defined in claim 21, wherein the  
monitoring means for automatically regulating operating  
parameters of the plasma separator apparatus comprises a  
hematocrit sensor for measuring the hematocrit of blood,  
15 interconnected with the plasma separator apparatus by  
limit switches, said hematocrit sensor comprising light  
emitting means for emitting light into a blood sample,  
first light detecting means for detecting light emitted  
from the light emitting means, said first light detecting  
20 means positioned to receive light emitted from the light  
emitting means into the blood sample to the first light  
detecting means along a first path, and the first light  
detecting means outputting a signal corresponding to the  
amount of light detected, second light detecting means for  
25 detecting light emitted from the light emitting means, said  
second light detecting means being positioned to receive  
light emitted from the light emitting means into the blood  
sample to the second light detecting means along a second  
path, such that light emitted from the light emitting means  
30 must travel farther to reach the second detecting means  
than to reach the first light detecting means, thereby  
forming a second path from the light emitting means to the  
second light detecting means which is longer than the first  
path from the light emitting means to the first light  
35 detecting means, and regulating means for regulating the

1 intensity of light emitted by the light emitting means such  
that the received light on one of the paths remains at a  
constant value.

5 29. A method for controlling the operation of a  
plasma separator apparatus by use of hematocrit measurement  
comprising the steps of:

10 (a) attaching a hematocrit sensor to a plasma  
separator apparatus wherein cellular components of  
blood, red blood cells, white blood cells, and  
platelets, are separated from waste components such as  
plasma, anticoagulant, toxins, and other relatively  
small molecules, said hematocrit sensor being capable  
of measuring the hematocrit level in blood;

15 (b) adjusting at least one operating parameter  
of the plasma separator apparatus in order to maintain  
the hematocrit within a predetermined range.

20 30. A method as defined in claim 29, wherein the step  
of adjusting at least one operating parameter of the plasma  
separator comprises joining the hematocrit sensor to the  
plasma separator apparatus by a microprocessor wherein  
various algorithms are programmed such that each hematocrit  
reading automatically produces a different and appropriate  
25 response from the plasma separator apparatus.

31. An optical connector for use with a hematocrit  
sensor comprising:

30 a generally hollow member adapted to receive a  
blood sample therein with respect to which hematocrit  
is to be measured; and

an optically clear flexible optical window  
positioned on the generally hollow member, and through  
which the blood sample within the generally hollow

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1 member may be visually accessed for measurement of its  
hematocrit.

32. An optical connector as defined in claim 31,  
5 wherein the flexible optical window comprises a  
polyvinylchloride resin material.

33. An apparatus for measuring the hematocrit of  
blood as defined in claim 31, further comprising a support  
10 extending from the flexible optical window substantially  
perpendicularly from the generally hollow member for  
securing to the cylindrical member a hematocrit sensor so  
as to allow measurement of the hematocrit of the blood  
sample within the generally hollow member.

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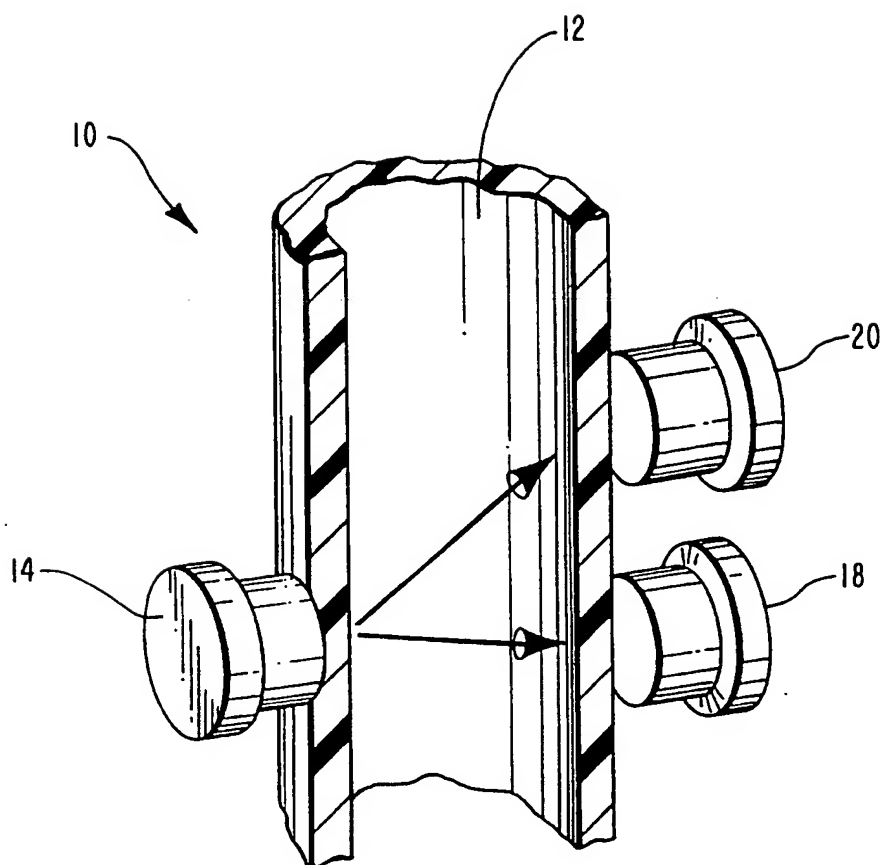


FIG. 1

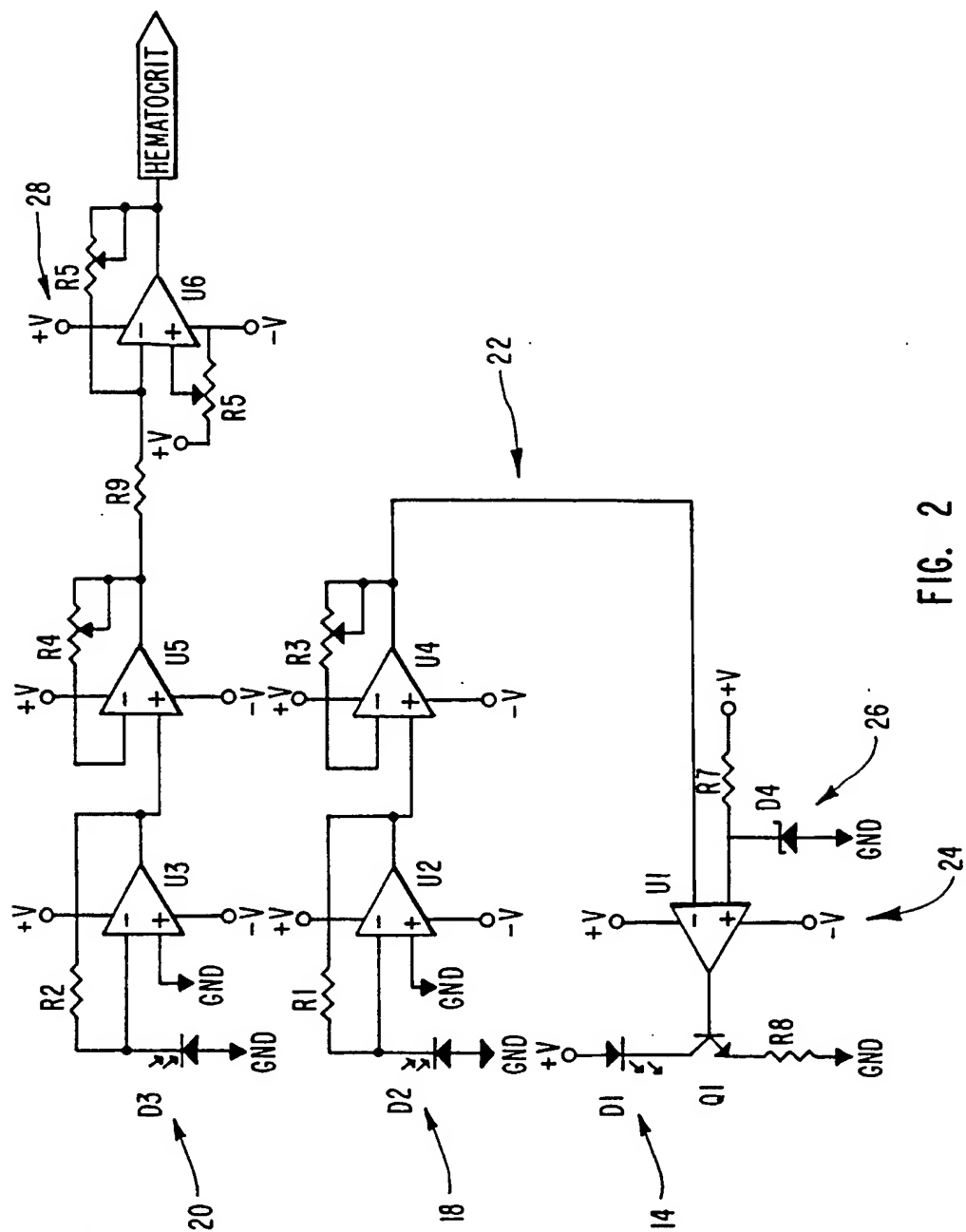


FIG. 2

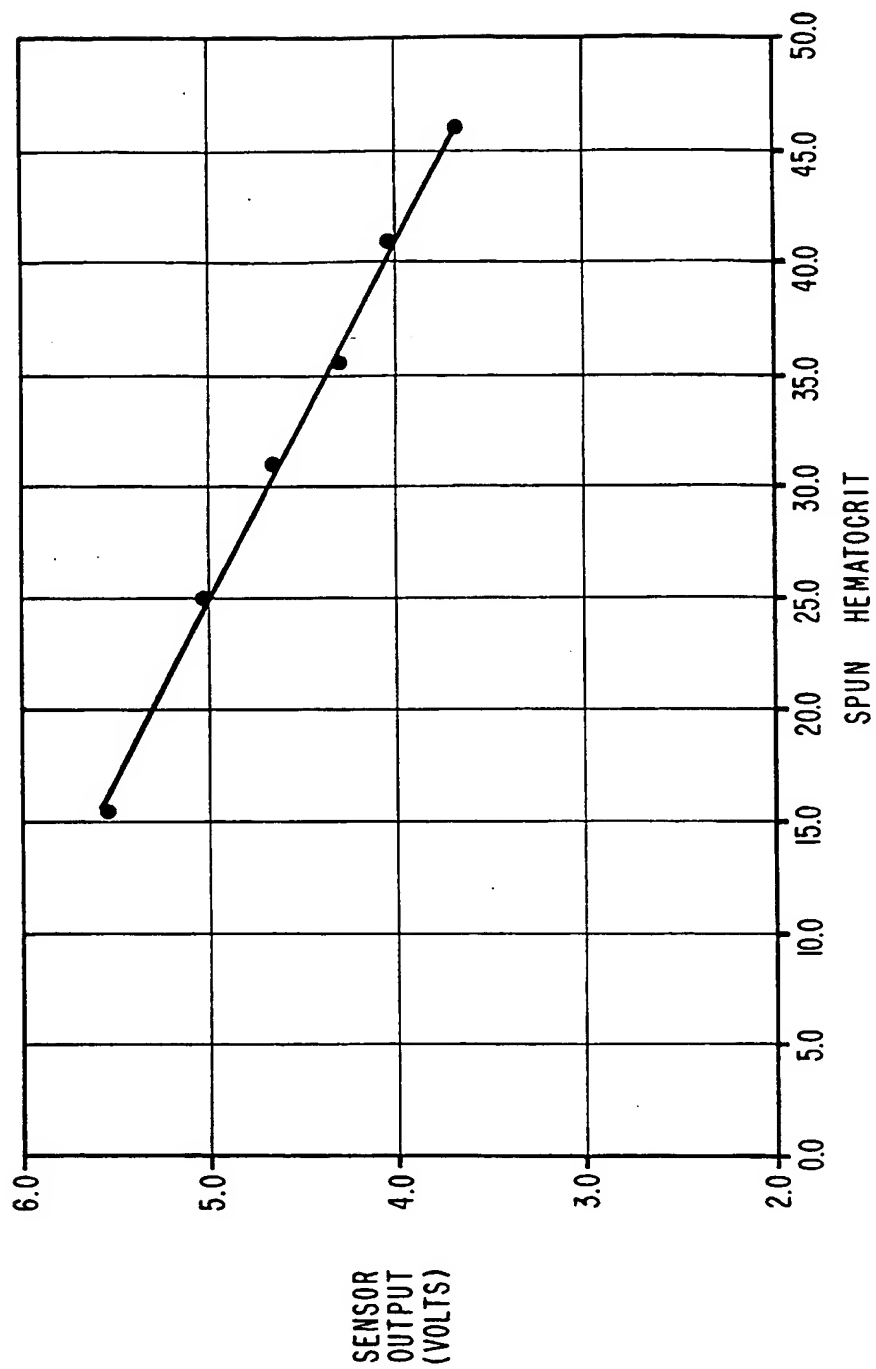


FIG. 3

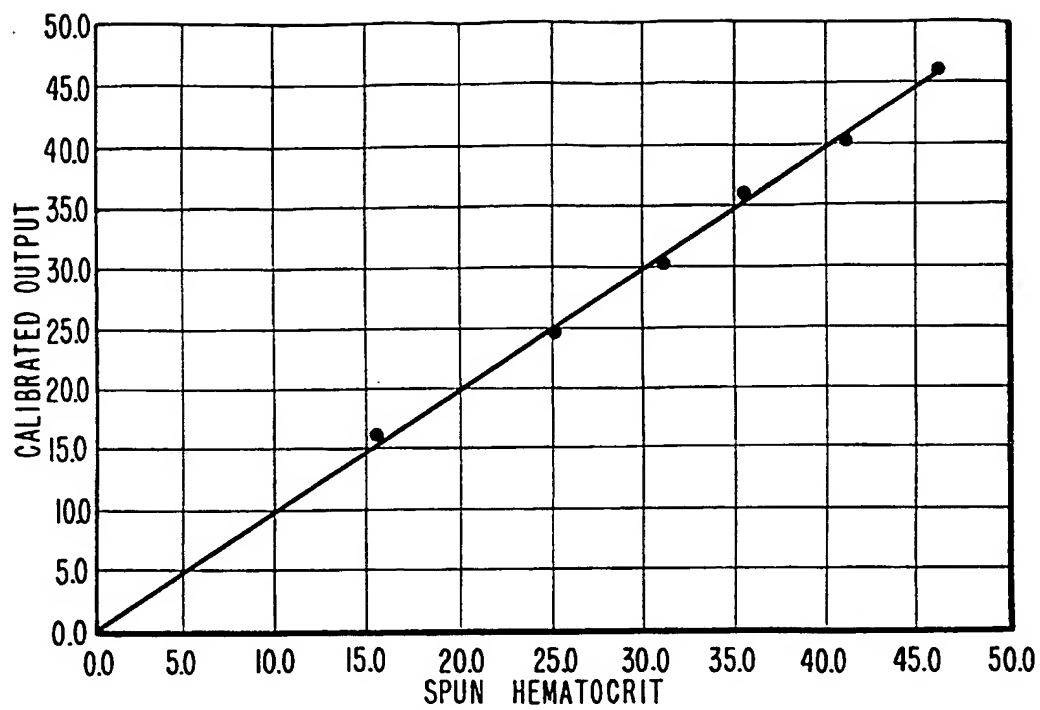


FIG. 4

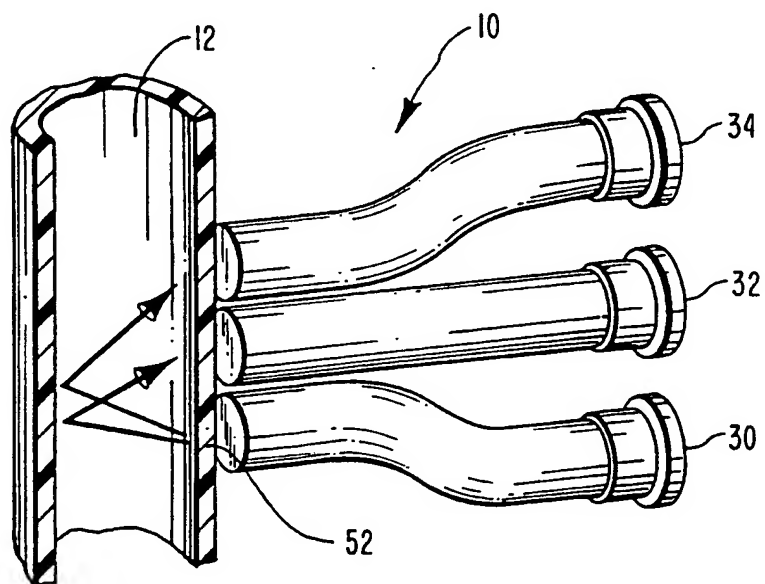
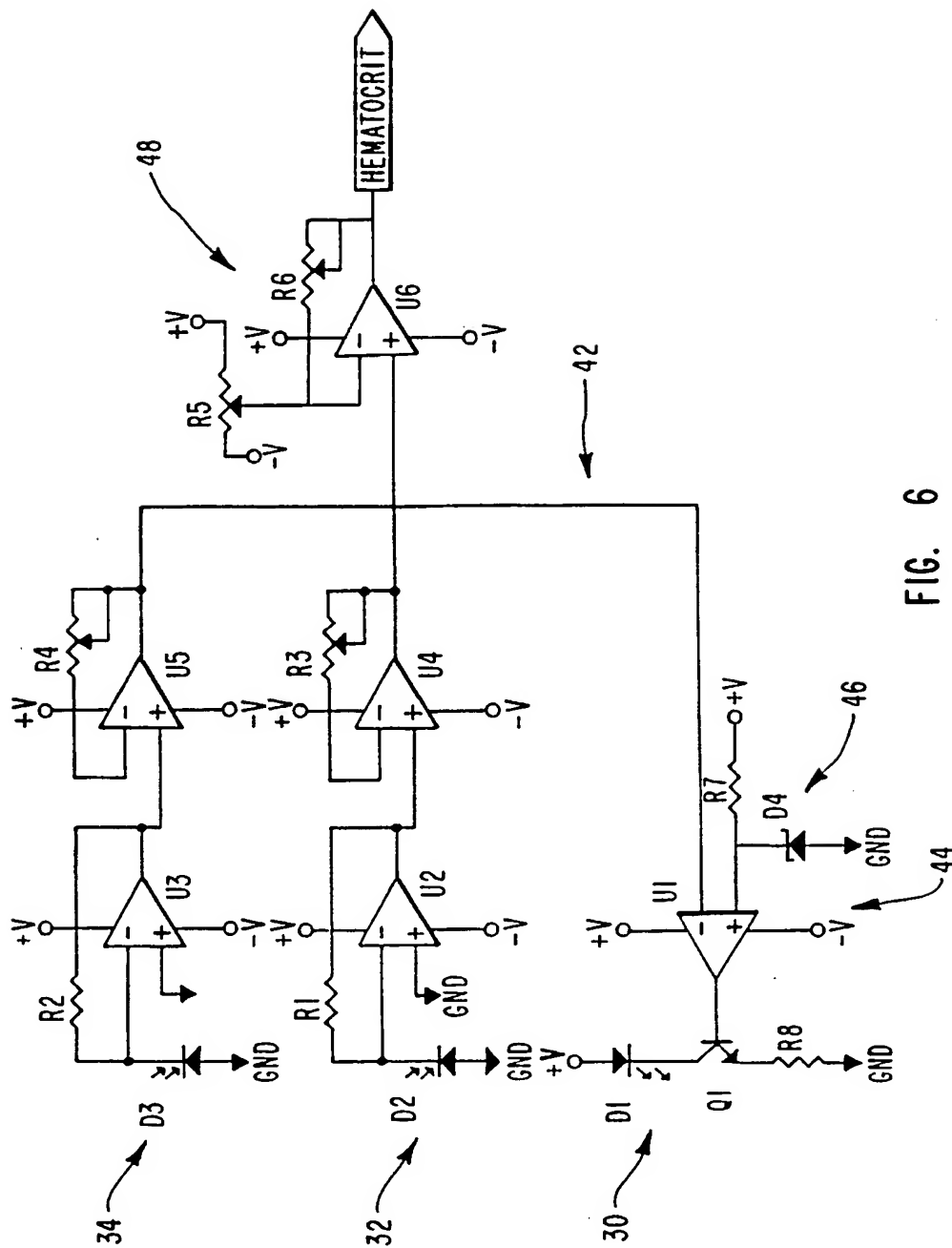


FIG. 5



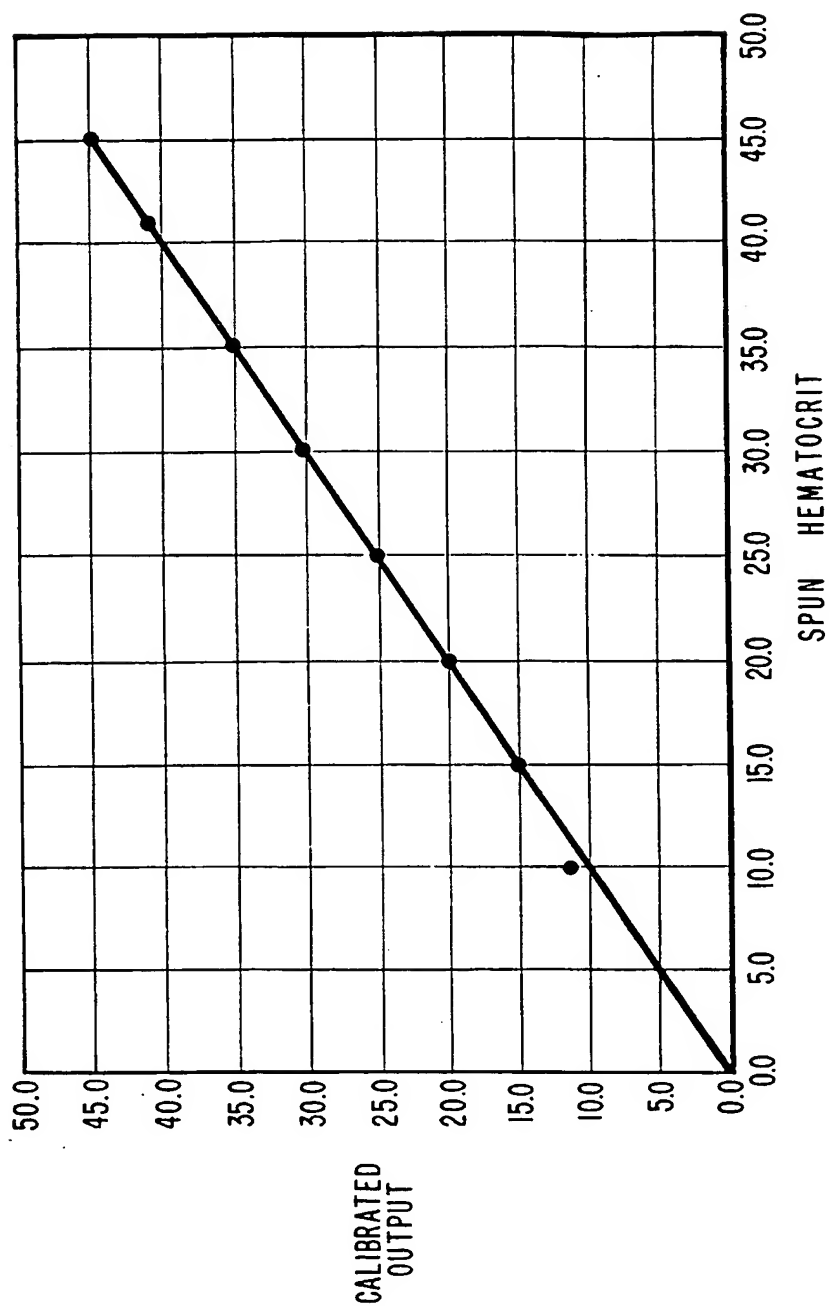


FIG. 7

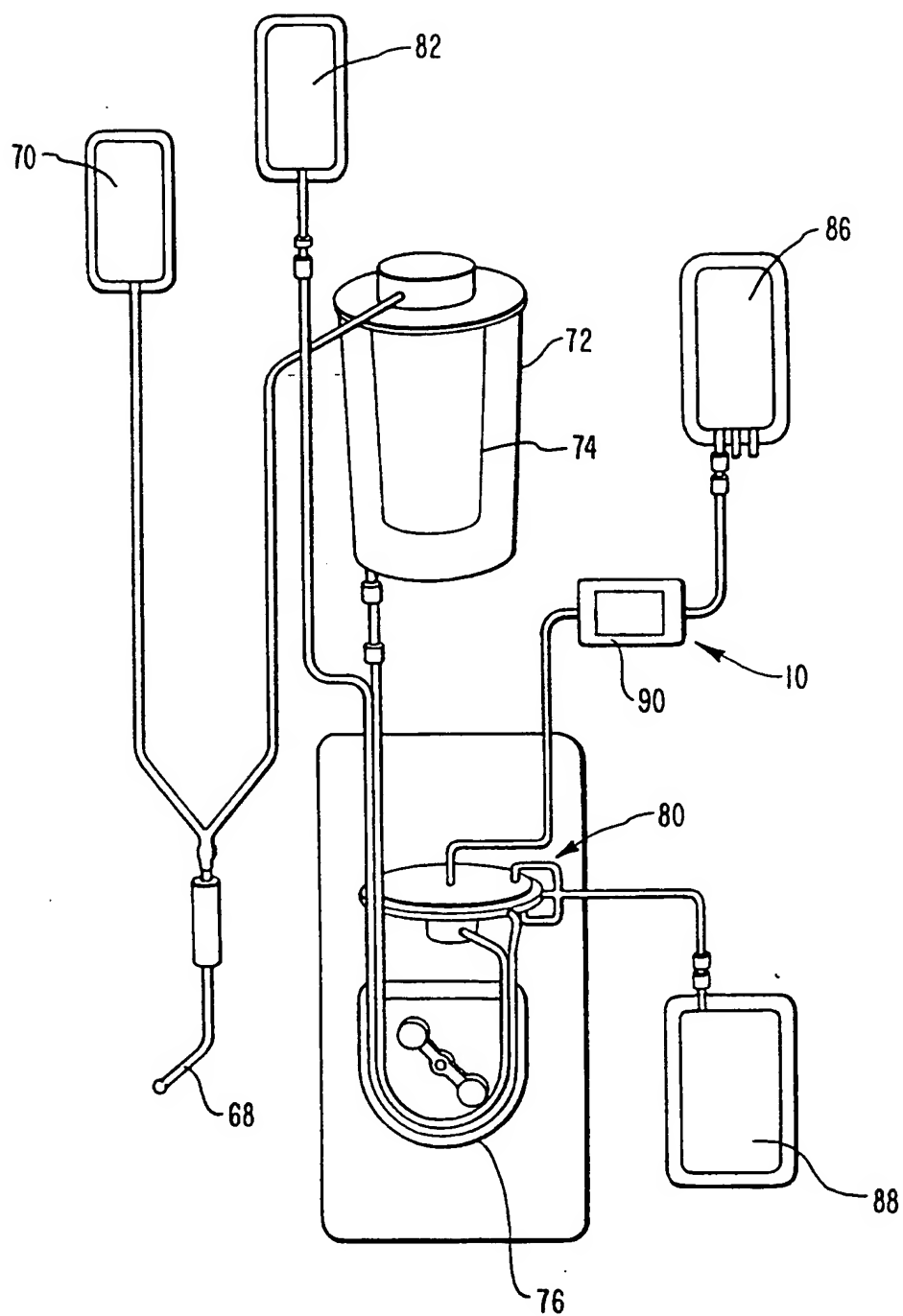


FIG. 8

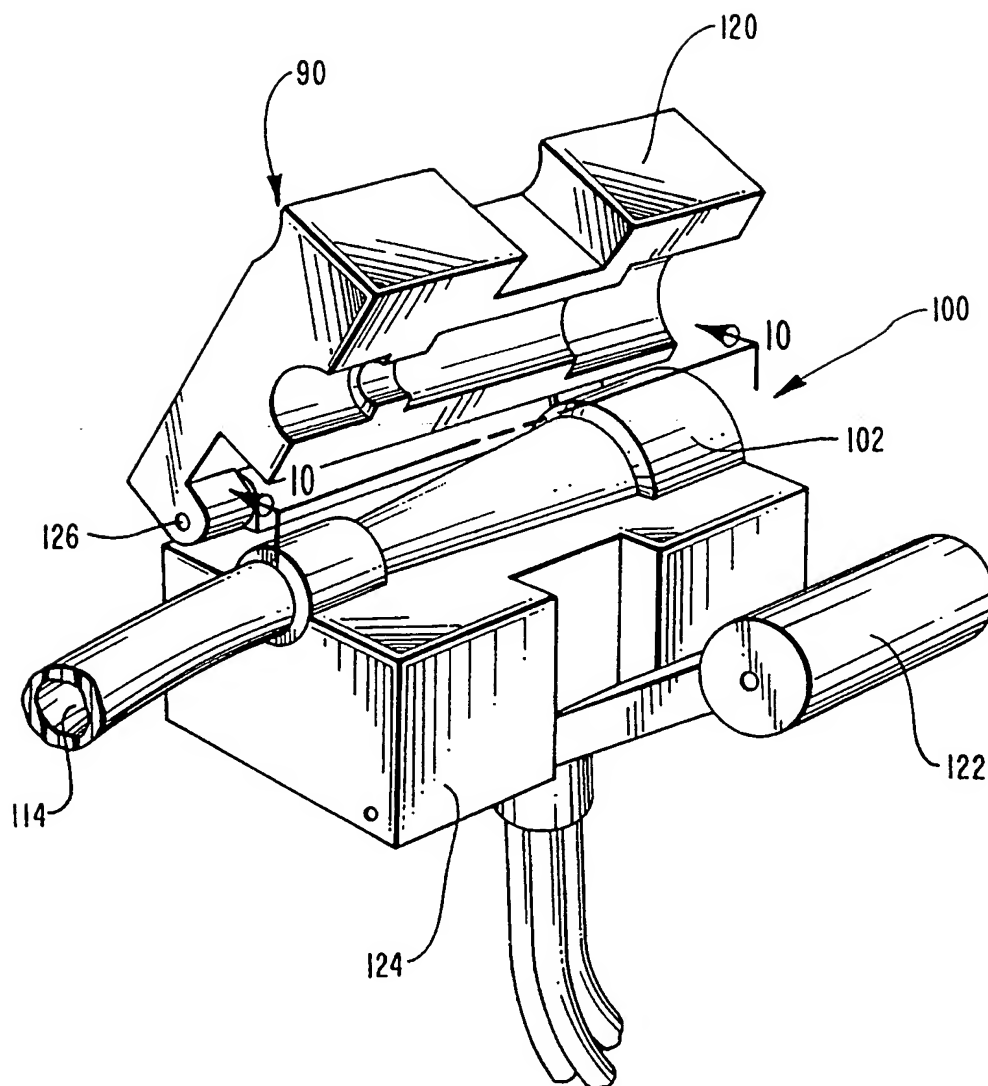


FIG. 9

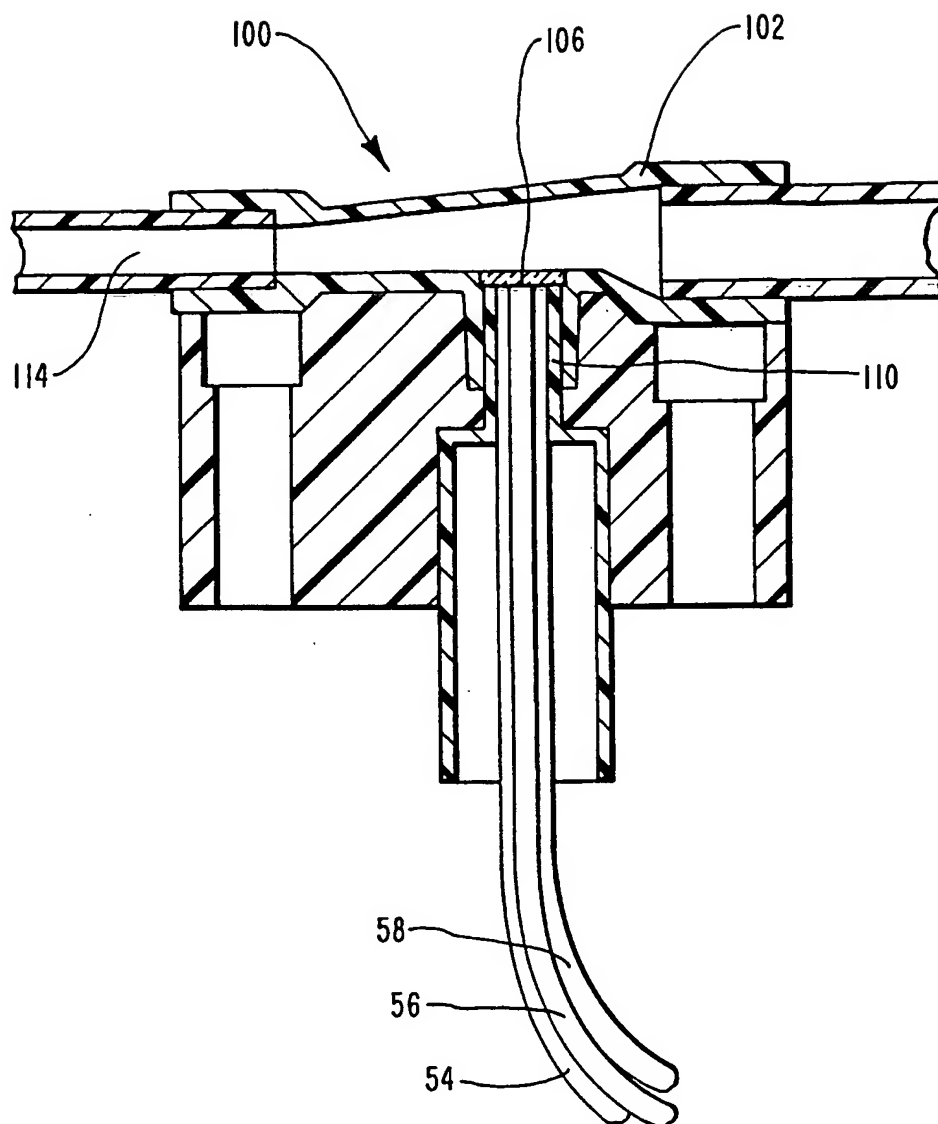


FIG. 10



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>5</sup> :</b>  <b>A61B 5/00</b>	<b>A3</b>	<b>(11) International Publication Number:</b> <b>WO 94/01749</b>  <b>(43) International Publication Date:</b> 20 January 1994 (20.01.94)
<b>(21) International Application Number:</b> PCT/US93/06057 <b>(22) International Filing Date:</b> 24 June 1993 (24.06.93)  <b>(30) Priority data:</b> 07/906,926                      30 June 1992 (30.06.92)                      US  <b>(71) Applicant:</b> ADVANCED HAEMOTECHNOLOGIES [US/US]; 2828 North Crescent Ridge Drive, The Woodlands, TX 77381 (US).  <b>(72) Inventor:</b> MAYNARD, David, L. ; 18 Ridgeline Court, The Woodlands, TX 77381 (US).  <b>(74) Agents:</b> SEELEY, David, O. et al.; Workman, Nydegger & Jensen, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).		<b>(81) Designated States:</b> JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>  <b>(88) Date of publication of the international search report:</b> 14 April 1994 (14.04.94)
<b>(54) Title:</b> APPARATUS AND METHODS FOR MONITORING HEMATOCRIT LEVELS OF BLOOD  <div data-bbox="565 1075 1140 1633" data-label="Image"> </div> <b>(57) Abstract</b>  <p>An apparatus and method are provided for measuring the hematocrit level of blood. The presently preferred embodiment comprises a light emitting device (14) which emits an amount of light into a blood sample (12). This light travels through the blood sample to two light detecting devices (18, 20) positioned relative to the light emitting device in a predetermined geometry such that light must travel farther to reach one of the light detecting devices than to reach the other. According to the present invention, the amount of light detected by one of the light detecting devices (18, 20) is regulated so that the amount of light detected is constant. Thereafter, the amount of light detected by the unregulated light detecting device is a linear representation of the hematocrit of the blood in the blood sample. The hematocrit sensor may be used to regulate the operating parameters of an autotransfusion system to maintain the hematocrit of the blood within a predetermined range.</p>		

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## INTERNATIONAL SEARCH REPORT

Int. l. application No.

PCT/US93/06057

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 5/00

US CL : 128/633

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/632-634; 150/338.1, 345; 356/39-41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,417,812, (Cserey et al.), 29 November 1983. See entire document.	1,6,7 ----- 1-5,8-24,27
X --- Y	US, A, 4,444,498, (Heinemann), 24 April 1984. See entire document.	31-33 ----- 2-28
Y, P	US, A, 5,178,603, (Prince), 12 January 1993. See entire document.	25-28

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